

## **REMARKS**

Claims 1, 22-26, and 31 are currently amended.

Claim 32 is canceled.

### **Drawings**

The Examiner has objected to the drawings under 37 CFR § 1.83(a). In particular the Examiner stated that the ultrasound transducer of claim 10 and the digestible composition of claim 11 (sic) must be shown or the feature(s) cancelled from the claims.

Applicants herewith submit new drawings, Figure 14 and Figure 15, Sheet 14/14, labeled “New Sheet” in compliance with 37 CFR § 1.121(d). Support for the new drawings is to be found in the application as filed on Figure 1 and in the specification at page 8, paragraph 37 (transducer) and at page 8, paragraph 38 (digestible composition). No new matter is hereby entered with this amendment.

### **Specification**

Applicants have amended the specification at page 8 to include element numbers of the elements identified on Figure 14 and Figure 15. No new matter is hereby entered with this amendment.

### **Claims**

Applicants have amended claims 1, 22, 26, and 31 to include a limitation of comprising a transducer. Support for the amendments to the claims is found in the specification at page 8, paragraph 37, line 1, wherein Applicants disclose that the heat exchange catheter “may additionally include a transducer”.

Claims 23 through 25 have been amended to correct claim dependency language.

Claim 32 has been canceled.

No new matter has been added by these amendments.

Applicants respectfully request entry of the present amendment.

Claim Rejections under 35 USC § 102(b)

1) The Examiner has rejected claims 1-4, 6, 8-9, 13-14, and 22-29 under 35 USC § 102(b) as being anticipated by Saab (USPN 5,624,392).

The Examiner stated that Saab discloses a heat exchange catheter system for cooling a target organ as recited in claims 1, 2, 3, 4, 6, 8, 9, 13, and 14. The Examiner stated that the heat exchange catheter system of Saab inherently cools a target organ, and therefore claims 1, 2, and 9 are anticipated by Saab.

The Examiner stated that the heat exchange catheter system of Saab discloses a thermal exchange composition within the balloon lumen wherein the thermal exchange composition flows within the continuous fluid pathway formed by the second elongate tubular body, the first elongate tubular body, and the balloon lumen and therefore claims 3, 4, and 8 are anticipated by Saab.

The Examiner stated that the heat exchange catheter system of Saab discloses the heat exchange catheter system wherein the balloon is shaped and sized for placement in the anatomical structure selected from the group consisting of: the venous system and therefore claim 6 is anticipated by Saab.

The Examiner stated that Saab further discloses the heat exchange catheter system of claim 1 further comprising a third elongate tubular body (74) having a proximal end and a distal end, the third elongate tubular body disposed longitudinally within the second elongate tubular body, and wherein the balloon is sealably affixed to the outer surface of the third elongate tubular body, and further comprising a guidewire disposed within the third elongate tubular body thereby anticipating claims 13 and 14.

Anticipation under 35 U.S.C. 102(b) requires the presence in a single prior art disclosure of each and every element of a claimed invention, *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747, 3 USPQ2d 1766, 1767 (Fed. Cir. 1987), cert. denied, 484 U.S. 1007 (1988).

Applicants respectfully submit that Saab does not disclose a heat exchange catheter system for cooling a target organ comprising a transducer. Applicants have amended claim 1 to recite : “A heat exchange catheter system for cooling a target organ, the heat exchange catheter system adapted for placement within an anatomical structure of a subject, comprising: (a) a first elongate tubular body 1 having a proximal end and a distal end, (b) a second elongate tubular body 2 having a proximal end and a distal end, (c) a transducer, and (d) a balloon 4 defining a lumen 8 in fluid communication with both the first elongate tubular body 1 and the second elongate tubular body 2 so as to form a continuous fluid pathway, and wherein the balloon, when inflated, is adapted to conform in shape and size to the interior of the anatomical structure such that when placed within the anatomical structure and inflated, the outer surface of the balloon is at least partially in contact with the inner surface of the anatomical structure providing a heat exchange surface by which heat is exchanged between the anatomical structure and interior of the balloon, and whereby the target organ adjacent to the anatomical structure is thereby cooled”.

Applicants submit that claim 1 as amended is not anticipated by Saab. Applicants respectfully note that since claims 2, 3, 4, 6, 8, 9, 13, and 14 are dependent upon claim 1, claims 2, 3, 4, 6, 8, 9, 13, and 14 are not anticipated by Saab. Applicants further submit that Saab does not disclose a solid or a gel as recited in instant claim 8.

Applicants therefore respectfully request that the Examiner withdraw the rejection of claims 1-4, 6, 8-9, and 13-14 under 35 USC § 102(b) as being anticipated by Saab.

The Examiner stated that Saab discloses all elements of claims 22-29 as presented above where the saccular body is the balloon that forms a flexible and inelastic reservoir.

Anticipation under 35 U.S.C. 102(b) requires the presence in a single prior art disclosure of each and every element of a claimed invention, *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747, 3 USPQ2d 1766, 1767 (Fed. Cir. 1987), cert. denied, 484 U.S. 1007 (1988).

Applicants respectfully submit that Saab does not disclose a heat exchange catheter system for cooling a target organ comprising a transducer. Applicants have amended claim 22 to recite : “A heat exchange catheter system for cooling a target organ, the heat exchange

catheter system comprising a transducer and an inflatable saccular body defining a lumen, adapted to conform in shape and size to the interior of an anatomical structure, wherein when placed within the anatomical structure and inflated, the outer surface of the saccular body is at least partially in contact with the inner surface of the anatomical structure providing a heat exchange surface by which heat is exchanged between the anatomical structure and the lumen of the saccular body, and whereby the target organ adjacent to the anatomical structure is thereby cooled.<sup>#</sup>

Applicants submit that claim 22 as amended is not anticipated by Saab. Applicants respectfully note that since claims 23, 24, and 25 are dependent upon claim 22, claims 23, 24, and 25 are not anticipated by Saab.

Applicants respectfully submit that Saab does not disclose a device for transesophageal cooling of the heart of a subject comprising a transducer. Applicants have amended claim 26 to recite: “A device for transesophageal cooling of the heart of a subject comprising: (a) a reservoir adapted in shape and size to conform to the lumen of the esophagus, (b) a thermal exchange composition disposed within the reservoir, and (c) a transducer”. Applicants submit that claim 26 as amended is not anticipated by Saab. Applicants respectfully note that since claims 27, 28, and 29 are dependent upon claim 26, claims 27, 28, and 29 are not anticipated by Saab.

Applicants therefore respectfully request that the Examiner withdraw the rejection of claims 1-4, 6, 8-9, 13-14, and 22-29 under 35 USC § 102(b) as being anticipated by Saab.

2) The Examiner has rejected claims 1-9, 13-14, and 22-34 under 35 USC § 102(b) as being anticipated by Lalonde et al. (USPN 6,283,959).

The Examiner stated that Lalonde et al. discloses all elements of claims 1-9 and 13-14 and that the device may be applied to cool the esophagus where inherently the heart will be cooled also by circulating of a gas or liquid and positioned by guidewire placed within the third elongate member or lumen.

The Examiner stated that Lalonde et al. discloses all elements of claims 22-30 as presented above where the saccular body is the balloon that forms a flexible and inelastic reservoir and, as an option for the coolant, liquid saline is provided by a pump as recited in claim 30.

The Examiner stated that Lalonde et al. discloses all the steps of claims 31-34 that would be inherent when the esophagus is cooled thus cooling the adjacent heart.

Anticipation under 35 U.S.C. 102(b) requires the presence in a single prior art disclosure of each and every element of a claimed invention, *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747, 3 USPQ2d 1766, 1767 (Fed. Cir. 1987), cert. denied, 484 U.S. 1007 (1988).

Applicants respectfully submit that Lalonde et al. does not disclose a heat exchange catheter system for cooling a target organ comprising a transducer. Applicants have amended claim 1 to recite : “A heat exchange catheter system for cooling a target organ, the heat exchange catheter system adapted for placement within an anatomical structure of a subject, comprising: (a) a first elongate tubular body 1 having a proximal end and a distal end, (b) a second elongate tubular body 2 having a proximal end and a distal end, (c) a transducer, and (d) a balloon 4 defining a lumen 8 in fluid communication with both the first elongate tubular body 1 and the second elongate tubular body 2 so as to form a continuous fluid pathway, and wherein the balloon, when inflated, is adapted to conform in shape and size to the interior of the anatomical structure such that when placed within the anatomical structure and inflated, the outer surface of the balloon is at least partially in contact with the inner surface of the anatomical structure providing a heat exchange surface by which heat is exchanged between the anatomical structure and interior of the balloon, and whereby the target organ adjacent to the anatomical structure is thereby cooled”.

Applicants submit that claim 1 as amended is not anticipated by Lalonde et al. Applicants respectfully note that since claims 2, 3, 4, 5, 6, 7, 8, 9, 13, and 14 are dependent upon claim 1, claims 2, 3, 4, 5, 6, 7, 8, 9, 13, and 14 are not anticipated by Lalonde et al.

Applicants further submit that Lalonde et al. do not disclose a solid or a gel as recited in instant claim 8.

Applicants respectfully submit that Lalonde et al. does not disclose a heat exchange catheter system for cooling a target organ comprising a transducer. Applicants have amended claim 22 to recite : “A heat exchange catheter system for cooling a target organ, the heat exchange catheter system comprising a transducer and an inflatable saccular body defining a lumen, adapted to conform in shape and size to the interior of an anatomical structure, wherein when placed within the anatomical structure and inflated, the outer surface of the saccular body is at least partially in contact with the inner surface of the anatomical structure providing a heat exchange surface by which heat is exchanged between the anatomical structure and the lumen of the saccular body, and whereby the target organ adjacent to the anatomical structure is thereby cooled”.

Applicants submit that claim 22 as amended is not anticipated by Lalonde et al.  
Applicants respectfully note that since claims 23, 24, and 25 are dependent upon claim 22, claims 23, 24, and 25 are not anticipated by Lalonde et al.

Applicants respectfully submit that Lalonde et al. does not disclose a device for transesophageal cooling of the heart of a subject comprising a transducer. Applicants have amended claim 26 to recite: “A device for transesophageal cooling of the heart of a subject comprising: (a) a reservoir adapted in shape and size to conform to the lumen of the esophagus, (b) a thermal exchange composition disposed within the reservoir, and (c) a transducer”.

Applicants submit that claim 26 as amended is not anticipated by Lalonde et al.  
Applicants respectfully note that since claims 27, 28, 29, and 30 are dependent upon claim 26, claims 27, 28, 29, and 30 are not anticipated by Lalonde et al.

Applicants respectfully submit that Lalonde et al. does not disclose a method for of altering the temperature of the myocardium of the heart of a subject comprising the steps of placing a thermal exchange composition within the esophagus of the subject, the thermal exchange composition contained in a reservoir, and the reservoir comprising a

transducer. Applicants have amended claim 31 to recite: "A method of altering the temperature of the myocardium of the heart in a subject, the method comprising the steps of: (a) providing a thermal exchange composition, and (b) placing the thermal exchange composition within the esophagus of the subject, whereby the myocardium of the heart is cooled and wherein the thermal exchange composition is contained within a reservoir and the reservoir comprises a transducer". Applicants have canceled claim 32 and included the limitations of claim 32 in amended claim 31.

Applicants submit that claim 31 as amended is not anticipated by Lalonde et al. Applicants respectfully note that since claim 33 is dependent upon claim 31, claim 33 is not anticipated by Lalonde et al.

Regarding claim 34, Applicants respectfully submit that Lalonde et al. do not disclose a heat exchange catheter system comprising a transducer as recited in claim 1 as amended. Applicants further submit that since claim 34 is a method of using the system of claim 3, claim 3 being dependent upon claim 1, that Lalonde et al. do not disclose a method of using a heat exchange catheter system as recited in claim 34.

Applicants therefore respectfully request that the Examiner withdraw the rejection of claims 1-9, 13-14, and 22-34 under 35 USC § 102(b) as being anticipated by Lalonde et al.

#### Claim Rejections under 35 USC § 103(a)

3) The Examiner has rejected claims 16-21 and 35-36 under 35 USC § 103(a) as being unpatentable over Lalonde et al. The Examiner stated that although Lalonde et al. failed to disclose the specific cooling rates claimed, the Examiner maintained that even the most rapid rate of 2-5 degrees per 30 minutes could be realized by the catheter system based upon typical performance of the disclosed coolants.

"Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined."  
*Graham v. John Deere Co.*, 148 USPQ 459, 467 (S.Ct. 1966).

Applicants respectfully submit that the scope and content of the prior art and the claims at issue are different in that Lalonde et al. does not disclose a heat exchange catheter system for cooling a target organ comprising a transducer. Of note, Applicants respectfully observe that the Examiner has not rejected independent claims 1 and 34, from which claims 16-21 and 35-36 respectively, depend upon. However, in order to advance prosecution and place the application in condition for allowance, Applicants have amended claim 1 to recite : “A heat exchange catheter system for cooling a target organ, the heat exchange catheter system adapted for placement within an anatomical structure of a subject, comprising: (a) a first elongate tubular body 1 having a proximal end and a distal end, (b) a second elongate tubular body 2 having a proximal end and a distal end, (c) a transducer, and (d) a balloon 4 defining a lumen 8 in fluid communication with both the first elongate tubular body 1 and the second elongate tubular body 2 so as to form a continuous fluid pathway, and wherein the balloon, when inflated, is adapted to conform in shape and size to the interior of the anatomical structure such that when placed within the anatomical structure and inflated, the outer surface of the balloon is at least partially in contact with the inner surface of the anatomical structure providing a heat exchange surface by which heat is exchanged between the anatomical structure and interior of the balloon, and whereby the target organ adjacent to the anatomical structure is thereby cooled”.

Applicants respectfully submit that Lalonde et al. and the subject matter sought to be patent are different such that the subject matter as a whole would not have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Lalonde et al. do not disclose a heat exchange catheter system comprising a transducer as recited in claim 1 and therefore dependent claims 16-21 are not unpatentable over Lalonde et al. Applicants further submit that since claim 34 is a method of using the system of claim 3, claim 3 being dependent upon claim 1, that Lalonde et al. do not disclose the method of using a heat exchange catheter system as claimed in claim 34 and therefore dependent claims 35 and 36 are not unpatentable over Lalonde et al..

Applicants therefore respectfully request that the Examiner withdraw the rejection of claims 16-21 and 35-36 under 35 USC § 103(a) as being unpatentable over Lalonde et al.



Allowable Subject Matter

4) The Examiner objected to claims 10-12 and 15 as being dependent upon a rejected base claim but would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims.

Applicants submit that claims 10-12 and 15 are dependent upon claim 1; Applicants have amended claim 1 to recite : “A heat exchange catheter system for cooling a target organ, the heat exchange catheter system adapted for placement within an anatomical structure of a subject, comprising: (a) a first elongate tubular body 1 having a proximal end and a distal end, (b) a second elongate tubular body 2 having a proximal end and a distal end, (c) a transducer, and (d) a balloon 4 defining a lumen 8 in fluid communication with both the first elongate tubular body 1 and the second elongate tubular body 2 so as to form a continuous fluid pathway, and wherein the balloon, when inflated, is adapted to conform in shape and size to the interior of the anatomical structure such that when placed within the anatomical structure and inflated, the outer surface of the balloon is at least partially in contact with the inner surface of the anatomical structure providing a heat exchange surface by which heat is exchanged between the anatomical structure and interior of the balloon, and whereby the target organ adjacent to the anatomical structure is thereby cooled”. Applicants have included the limitation of a transducer as an element of the system of claim 1 thereby overcoming the rejection of the Examiner of the base claim (claim 1).

Applicants therefore respectfully request that the Examiner withdraw the objection to claims 10-12 and 15.

**CONCLUSION**

With the above amendments and arguments, Applicants submit that the instant application is in condition for allowance.

If the US Patent Office believes that communication would further the prosecution of this application, then the appropriate US Patent Office personnel are invited to contact the Applicants' below-signed representative at their earliest convenience.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Bell & Associates Deposit Account No. 50-3194.

Dated and signed:

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